

K002732

OCT - 2 2000

**stryker**  
**LEIBINGER**

4100 East Milham Avenue  
Kalamazoo, MI 49001  
Phone (616) 323-7700  
(800) 253-7370

**Device Name:**

Trade Name: Stryker Navigation System ENT Module  
Common Name: Image Guided Surgery System  
Classification Name: Instrument, Stereotaxic: 21 CFR 882.4560, Class II

**Device Sponsor:**

Manufacturer: Stryker Corporation  
Stryker Leibinger GmbH and Co. KG  
Boetzinger Straße 41  
D-79111 Freiburg Germany  
Registration No.: 8010177

Distributor: Stryker Corporation  
Stryker Leibinger  
4100 E. Milham Avenue  
Kalamazoo, MI 49001  
Registration No.: 1811755

**Regulatory Class:** Class II

**Summary of Safety and Effectiveness:**

The Stryker Navigation System - ENT Module is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system is indicated for any medical condition in which the use of image guided surgery may be appropriate, and where a reference to a rigid anatomical structure can be identified relative to medical images. The ENT Module is also indicated for intranasal or sinus use.

The Stryker Navigation System - ENT Module is equivalent in intended use, safety, and effectiveness to existing image guided surgery systems begin marketed by companies such as Stryker and Sofamor Danek.

The Stryker Navigation System - ENT Module provides precise stereotactic determination of surgical targets using a stereotactic methodology. The three principle features include computer calculation of stereotactic coordinates from the diagnostic images, measurement of stereotactic coordinates within the surgical field, high-resolution computer display of diagnostic images with stereotactic coordinates indicated. The system is comprised of hardware and software components.

The Stryker Navigation System - ENT Module does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Navigation System - ENT Module is substantially equivalent to these existing devices.

By: Nicole Petty  
Nicole Petty  
Regulatory Analyst

Dated: 8-31-00



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 2 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Nicole Petty  
Regulatory Affairs Analyst  
Stryker Corporation  
Stryker Leibinger  
4100 East Milham Avenue  
Kalamazoo, Michigan 49001

Re: K002732  
Trade Name: Stryker Navigation System - ENT Module  
Regulatory Class: II  
Product Code: HAW  
Dated: August 31, 2000  
Received: September 1, 2000

Dear Ms. Petty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Nicole Petty

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

*for Mark N. Milburn*

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K002732

Device Name: Stryker Navigation System – ENT Module

Indications For Use: The Stryker Navigation System – ENT Module is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system is indicated for any medical condition in which the use of image guided surgery may be appropriate, and where a reference to a rigid anatomical structure can be identified relative to medical images. The ENT Module is also indicated for intranasal or sinus use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

Mark N. Milken  
(Division Sign-Off)

Division of Restorative Devices

510(k) Number K002732

(Optional Format 1-2-96)